

### **REMARKS/ARGUMENTS**

Claims 20, 67 and 72-85 are pending in the present application. Claims 20, 67 and 72-85 were rejected in the Office Action. Claims 20, 67 and 76 have been amended. No new matter has been added. Reexamination and reconsideration of the amended claims is respectfully requested.

#### **Claim Rejections - 35 U.S.C. § 102**

Claims 20, 67, 72-82 and 84-85 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,165,183 to Kuehn et al. (hereinafter referred to as Kuehn). Such rejection is traversed in part and overcome in part for at least the following reasons.

Independent claim 20 has been amended to recite an apparatus for repairing a valve in a patient's body, the valve having a plurality of movable leaflets, the leaflets having a superior surface on a first side and an inferior surface on an opposing side, the apparatus comprising:

a pair of articulating arms coupled together and movable from an open position in which portions of the articulating arms are spaced apart to a closed position in which the portions of the articulating arms are closer together, the arms being configured to engage the inferior surfaces of the leaflets and hold the leaflets in a coapted configuration in which portions of the superior surfaces are facing each other;

a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms, wherein the arms can be closed to engage the leaflets and thereafter be opened to allow release of the leaflets;

a central member coupled to a shaft, the shaft adapted for delivering the articulating arms into a heart, the central member being detachable from the shaft while the shaft is in the patient's body, and the articulating arms being movably coupled to the central member and implantable in the patient's body to maintain the leaflets in the coapted configuration after the shaft has been removed from the patient's body; and

a pair of superior elements movably coupled to the central member, the superior elements being configured to engage the superior surfaces whereby the leaflets may be pinched between the articulating arms and the superior elements and wherein the superior elements are resiliently biased into an extended configuration in which portions of the superior elements are spaced apart from the central member for engaging the superior surfaces of the leaflets.

Support for this amendment may be found in Figs. 87A-87C and paragraph 0164 of the application as filed, therefore no new matter has been added. Kuehn fails to disclose each and every element of amended claim 20.

Fig. 20 of Kuehn describes a gripper 438 having graspers 440 used to grasp valve leaflets 122, 124 (col. 9, lines 49-50). Kuehn discloses that spring loaded graspers 440 are drawn toward plunger 446 or 454 in order to entrap the valve leaflets, by pulling shaft 456 (col. 9, lines 57-59). Graspers 440 therefore translate linearly and Kuehn fails to teach or suggest that graspers 440 have a hinge or pivot connection that would be required if graspers 440 were articulated and thus the cited reference fails to teach or suggest that graspers 440 are a pair of articulating arms, as claim 20 requires. Furthermore, because graspers 440 in Fig. 20 move linearly, Kuehn also fails to teach or suggest that the graspers are movable from an open position in which portions of the articulating arms are spaced apart to a closed position in which the portions of the articulating arms are closer together, also required by claim 20.

Claim 20 also recites in part that the articulating arms are implantable in the patient's body to maintain the leaflets in the coapted configuration. While graspers 440 in Fig. 20 of Kuehn are temporarily placed in a patient's body, after the leaflets 122, 124 are fastened, graspers 440 are withdrawn (col. 9, line 67 - col. 10, line 2). Because graspers 440 are withdrawn, they are not implantable into a patient's body as claim 20 requires. Nevertheless, in order to further distinguish the cited reference from the claimed invention, claim 20 has been amended to recite in part that the articulating arms are implantable in the patient's body to maintain the leaflets in the coapted configuration after the shaft has been removed from the patient's body. Because the graspers in Kuehn are withdrawn, they cannot remain in the patient's body as amended claim 20 requires.

As previously mentioned, in Fig. 20, Kuehn discloses that spring loaded graspers 440 are drawn toward plunger 446 or 454 by pulling shaft 456 (col. 9, lines 57-59). Graspers 440 therefore translate linearly to clasp leaflets 122, 124 between graspers 440 and grasper tube 441 (col. 9, lines 61-65). Since graspers 440 slide linearly during leaflet capture, Kuehn fails to teach or suggest a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms, wherein the arms can be closed to engage the leaflets and thereafter be opened to allow release of the leaflets, as required by claim 20.

Claim 20 also recites in part a central member detachable from the shaft. Applicants respectfully disagree with the Examiner's characterization that the entire device in Kuehn may be disassembled. Kuehn fails to disclose anywhere that the entire device may be disassembled. Nevertheless, in order to further distinguished claim 20 from the cited reference, claim 20 has been amended to recite in part that the central member is detachable from the shaft while the shaft is in the patient's body.

Claim 20 also requires that the articulating arms are movably coupled to the central member. Kuehn also fails to disclose this limitation because in Fig. 20, Kuehn only discloses two or more arms 450, 452 (col. 9, line 52). Kuehn fails to teach or suggest that these elements are movably coupled to the same central member to which graspers 440 are coupled. Moreover, Kuehn fails to disclose that the arms are resiliently biased into an extended configuration as claim 20 also requires.

Because the cited reference fails to teach or suggest each and every element of claim 20, anticipation under 35 U.S.C. § 102(e) cannot be established. Applicants respectfully request withdrawal of the § 102(e) rejection and allowance of independent claim 20 and the claims which depend therefrom.

Independent claim 67 was rejected under 35 U.S.C. § 102(e) as being anticipated by Kuehn. Such rejection is traversed in part and overcome in part for at least the following reasons.

Independent claim 67 has been amended to recite an apparatus for repairing a valve in a patient's body, the valve having a plurality of moveable leaflets, the leaflets having a

superior surface on a first side and an inferior surface on an opposing side, the apparatus comprising:

a flexible shaft having a proximal end and a distal end;

a pair of articulating arms coupled together near the distal end of the flexible shaft and being moveable from an open position in which portions of the articulating arms are spaced apart to a closed position in which the portions of the articulating arms are closer together and to positions therebetween, the arms being configured to engage the inferior surfaces of the leaflets and hold the leaflets in a coapted configuration in which portions of the superior surfaces are facing each other;

a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms; and

a pair of superior elements movably coupled, the superior elements configured to engage the superior surfaces whereby the leaflets may be engaged between the articulating arms and the superior elements,

wherein the articulating arms and superior elements are moved independently of one another and can be closed to engage the leaflets and thereafter be opened to allow release and recapture of the leaflets prior to implantation of the articulating arms in the patient's body to maintain the leaflets in the coapted configuration after the flexible shaft has been removed.

Support for this amendment may be found in Figs. 87A-87C and paragraph 0164 of the application as filed, therefore no new matter has been added. Kuehn fails to disclose each and every element of amended claim 67.

As discussed above, in Fig. 20, Kuehn describes a gripper 438 having graspers 440 used to grasp valve leaflets 122, 124 (col. 9, lines 49-50). Kuehn discloses that spring loaded graspers 440 are drawn toward plunger 446 or 454 by pulling shaft 456 (col. 9, lines 57-59). Graspers 440 therefore translate linearly, thus Kuehn fails to teach or suggest that graspers 440 have a hinge or pivot connection that would be required to move graspers 440 in a non-linear fashion, therefore Kuehn fails to disclose that graspers 440 are a pair of articulating arms, as claim 20 requires. Furthermore, because graspers 440 move linearly, Kuehn also fails to teach or suggest that the graspers are movable from an open position in which portions of the

articulating arms are spaced apart to a closed position in which the portions of the articulating arms are closer together. Nevertheless, to further distinguish claim 20 from the cited reference, claim 20 has been amended to recite in part that the pair of articulating arms are coupled together near the distal end of the flexible shaft and being moveable from an open position in which portions of the articulating arms are spaced apart to a closed position in which the portions of the articulating arms are closer together and to positions therebetween. Because graspers 440 in Kuehn are drawn toward plunger 446, Kuehn fails to disclose that graspers 440 are openable to positions in between the open and closed positions as amended claim 67 now requires.

As discussed, Kuehn discloses in Fig. 20 that spring loaded graspers 440 are drawn toward plunger 446 or 454 by pulling shaft 456 (col. 9, lines 57-59). Graspers 440 therefore translate linearly to clasp leaflets 122, 124 between graspers 440 and grasper tube 441 (col. 9, lines 61-65) and graspers 440 do not open and close to clasp the leaflets. Kuehn therefore fails to teach or suggest a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms, as required by claim 67.

Additionally, graspers 440 in Fig. 20 of Kuehn are temporarily placed in a patient's body to maintain the leaflets in the coapted position. After the leaflets are fastened, graspers 440 are withdrawn (col. 9, line 67 - col. 10, line 2). Because graspers 440 are withdrawn, they are not implanted into the patient's body. To further emphasize this, claim 67 has been amended to recite in part that the articulating arms and superior elements are moved independently of one another and can be closed to engage the leaflets and thereafter be opened to allow release and recapture of the leaflets prior to implantation of the articulating arms in the patient's body to maintain the leaflets in the coapted configuration after the flexible shaft has been removed. Because Kuehn's graspers in Fig. 20 are withdrawn, they clearly do not remain in the patient's body after the shaft has been removed.

Because Kuehn fails to disclose each and every element of claim 67, anticipation cannot be established under 35 U.S.C. § 102(e). Applicants therefore respectfully request withdrawal of § 102(e) rejection and allowance of claim 67 and the claims which depend therefrom.

Claim Rejections - 35 U.S.C. § 103

Claim 83 was rejected under 35 U.S.C. § 103(a) as being obvious over Kuehn in view of U.S. Patent No. 6,269,819 to Oz et al. (hereinafter referred to as Oz). Such rejection is overcome for at least the following reasons.

Claim 83 depends from independent base claim 67 which has been distinguished from Kuehn above. Oz fails to provide the elements missing from Kuehn. Oz discloses an apparatus for the repair of a cardiovascular valve comprising a grasper having articulating arms that are capable of grabbing and coapting the valve leaflets (Abstract). Once the leaflets are coapted, they are fastened together with a fastener that is detachably coupled to the grasper arms. The fastener is left in the patient but the grasper is removed from the patient and thus the articulating arms in Oz do not remain in the patient. Since the grasper in Oz is not left in the patient, the cited reference fails to teach or suggest implantation of the articulating arms in the patient's body to maintain the leaflets in the coapted configuration after the flexible shaft has been removed, as required by claim base claim 67.

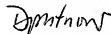
Because the cited references alone or in combination fail to disclose each and every element of claim 83, *prima facie* obviousness under 35 U.S.C. § 103(a) cannot be established. Applicants therefore request that the § 103(a) rejection be withdrawn and claim 83 be allowed.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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